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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/808,885  | 03/14/2001  | Jennifer L. Hillman  | PF-0354-2 DIV       | 5250             |
| 27904   | 7590        | 10/07/2003           | EXAMINER            |                  |
| INCYTE CORPORATION (formerly known as Incyte<br>Genomics, Inc.)<br>3160 PORTER DRIVE<br>PALO ALTO, CA 94304 |             |                      | HARRIS, ALANA M     |                  |
|   |             | ART UNIT             | PAPER NUMBER        |                  |
|   |             | 1642                 |                     |                  |

DATE MAILED: 10/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**DETAILED ACTION**

***Response to Arguments and Amendments***

1. Claims 3-19 are pending.

Claims 4, 7, 9, 18 and 19, drawn to non-elected inventions are withdrawn from examination.

Claim 3 has been amended.

Claims 3, 5, 6, 8 and 10-17 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 3, 5, 6, 8 and 10-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the claim amendment.

4. The rejection of claims 3, 5, 6, 8 and 10-17 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn.

5. The rejection of claims 3, 5, 6, 8 and 10-17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

***Maintained Rejection***

***Claim Rejections - 35 USC § 112/ Claim Rejections - 35 USC § 101***

6. The rejection of claims 3, 5, 6, 8 and 10-17 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and a substantial asserted utility or a well established utility is maintained.

Applicants argue that “[they] have identified the claimed polypeptide by association in a defined and narrow group”. Applicants continue to argue that the Examiner is wrong on the facts, differential expression in toxicology testing is irrelevant and the office action is based on flawed assumptions. These arguments have been carefully considered but found unpersuasive.

Applicants should note that the examined group is drawn to an isolated antibody and not a polypeptide as cited in Remarks, page 6, section A. Remiss from Applicants' specification is the particulars of toxicology testing with the claimed antibody, which allegedly binds SEQ ID NO: 1. There is no indication of the toxic substances nor the susceptible organ systems that would benefit from the claimed antibody. This utility would apply to virtually every member of a general class of materials, such as any collection of antibodies, but is only potential with respect to antibodies that bind SEQ ID

NO: 1. Such a utility is not specific and does not constitute a “well-established” utility. Any potential diagnostic utility is not yet known and has not yet been disclosed and the utility is not substantial because it is not currently available in a practical form. Even if the expression of Applicants’ SEQ ID NO: 1 are affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result and none is known in the art. As noted in previous Office Actions further experimentation on the claimed material itself is necessitated in order to determine what “use” any information regarding this claimed antibody. Furthermore, in the absence of any disclosed relationship between the claimed antibodies with any known disease or disorder, any information obtained from an expression profile would serve as the basis for further research on the observation itself.

Claims 3, 5, 6, 8 and 10-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The factors regarding the claimed antibody have been carefully considered in the instant grounds of rejection, and it is maintained.

### ***Conclusion***

**7. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



Alana M. Harris, Ph.D.  
1 October 2003